

Genetic Immunity Grants Exclusive License of Therapeutic HIV Vaccine Technology to JSC Pharmadis for Russian and Commonwealth of Independent States

December 18, 2018. Genetic Immunity, a clinical stage biotechnology company, has granted an exclusive license of its trans-dermally delivered pDNA-based therapeutic HIV vaccine technology to Pharmadis, a Russian company with vast experience in medicine.

Under terms of the agreement, effective immediately, Pharmadis received rights to market Genetic Immunity's HIV technology in Russia and the Commonwealth of Independent States. As part of the agreement, to qualify for Russian marketing approval, a new clinical study will be conducted in Moscow. Up to 200 patients will be enrolled in the study, expected to start in H1-2019 and to be completed in H1-2020.

Upon successful completion, marketing authorization will be sought. Pharmadis is responsible for financing study costs and seeking marketing approval.

"DermaVir is the next generation of plasmid DNA-based vaccine for the treatment of chronic diseases," stated Viktor Rozsnyay, CEO of Genetic Immunity. "We are very excited to partner with Pharmadis, one of the most professional medical companies in Russia, and are confident that together we can bring our HIV technology to the market."

"We look forward to facilitating the upcoming trial and hope for a positive outcome. Once approved in Russia, our therapeutic vaccine can be a significant addition to the treatment repertoire available to effectively combat HIV," Rozsnyay continued.

The DermaVir platform contains a novel plasmid DNA that encodes most HIV genes. The vaccine is administered topically using the DermaPrep medical device.

'Proof of concept' for the immunological and anti-viral activities of DermaVir was demonstrated in infected macaques, some of them with advanced stages of SIV. Analyses of data derived from these animal trials have indicated that repeated DermaVir administration results in a cumulative strengthening of the antiviral immune response without adding significant toxicities or adverse effects.

"In addition to the Russian license, we are in the process of completing documents requested by the FDA. Once available, data obtained in Russia will be used to strengthen our US submission process," Rozsnyay added.

"We are glad to begin cooperation with Genetic Immunity. We consider DermaVir potentially as the most revolutionary plasmid DNA-based therapeutic vaccine," stated Nikolai Kovalev, Managing Director of Pharmadis.

"We will do our best to support the clinical trial planned for 2019 in Moscow, and expect to see a positive outcome," added Kovalev.

Plasmid DNA-based vaccines have been proven safe, but poorly immunogenic in human subjects. Genetic Immunity has developed several technologies to improve the immunogenicity of DNA-encoded antigens, including:

- Antigeneering of plasmid DNA to safely and authentically express most of the antigens of HIV or other pathogens, including cancer.
- The formulation of plasmid DNA to a pathogen-like nanoparticle called NanoComp. These nanoparticles target professional antigen-presenting cells, such as Langerhans cells and dendritic cells.
- A targeted transdermal delivery device called DermaPrep. It has been shown that topical DermaPrep administration results in antigen expression in the lymph nodes by dendritic cells.

"Following successful preclinical studies, we completed a Phase I, Phase I/II, conducted by the AIDS Clinical Trials Group and funded by the National Institutes of Health in the USA, and a Phase II trial."

"In these studies, we have successfully demonstrated that DermaVir immunization induces new, HIV-specific memory T-cells that correlated to the amount of nanomedicine the subject received. Our data to date supports proof of concept, the relationship between DermaVir-induced antiviral immune responses and clinical benefit," concluded Rozsnyay.

About Genetic Immunity

Genetic Immunity is a development stage biotechnology company focusing on therapeutic vaccine research. The company's proprietary platform technology is based on trans-dermally delivered pDNA that can be effective in boosting the immune system to fight diseases, including viral infection like HIV, various cancers, allergies, and more. Genetic Immunity's lead product candidate for the treatment of HIV has completed three clinical trials to date with well-established immune-boosting properties. Building on the HIV data to date, the Company is now expanding its product portfolio to several cancer indications.

About Pharmadis

Pharmadis is one of the largest medical distribution companies in Russia with four primary divisions: Pharmaceuticals, Consumable Medical Goods, Medical Equipment, and Technical Support and Engineering. The company has authorizations from numerous international medical companies, including Johnson & Johnson, Baxter, Siemens, Philips, GE, Bayer, among many others. Pharmadis is consistently expanding its activity to implement innovative solutions in medicine in Russia.

For further information please contact Viktor Rozsnyay, CEO, Genetic Immunity,
viktor@geneticimmunity.com

Media enquiries: Vladislav Shayman, Managing Partner, Expertise Institute,
vladislav.shayman@gmail.com